

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

Allyson Netwall on behalf of herself and all others similarly situated

DEFENDANTS

Shire U.S., Inc. & Shire LLC

(b) County of Residence of First Listed Plaintiff Delaware
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant Delaware
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

(c) Attorneys (Firm Name, Address, and Telephone Number)

Ruben Honik, Esq., Kenneth Grunfeld, Esq., Tammi Markowitz Esq.
Golomb & Honik, P.C.
1515 Market Street, Ste. 1100, Philadelphia, PA 19102 (215)985-9177

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
☐ 2 U.S. Government Defendant
☐ 3 Federal Question (U.S. Government Not a Party)
☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | PTF | DEF | | PTF | DEF |
|---|---------------------------------------|---------------------------------------|---|----------------------------|----------------------------|
| Citizen of This State | <input checked="" type="checkbox"/> 1 | <input checked="" type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input checked="" type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	PERSONAL INJURY <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/ Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input checked="" type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding
☐ 2 Removed from State Court
☐ 3 Remanded from Appellate Court
☐ 4 Reinstated or Reopened
☐ 5 Transferred from Another District (specify)
☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
 28 U.S.C. § 1332(d)

Brief description of cause:
 Violation of Pennsylvania's Unfair Trade Practices and Consumer Protection Law & Unjust Enrichment

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$
 5,000,000.00

CHECK YES only if demanded in complaint:
 JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

DOCKET NUMBER

DATE
 03/26/2013

SIGNATURE OF ATTORNEY OF RECORD



FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

CASE MANAGEMENT TRACK DESIGNATION FORM

ALLYSON NETWALL ON BEHALF OF HERSELF	:	CIVIL ACTION
AND ALL OTHERS DIMILARLY SITUATED	:	
	:	
v.	:	
SHIRE U.S., INC. & SHIRE, LLC	:	NO.
	:	

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

- (a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ()
- (b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ()
- (c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ()
- (d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ()
- (e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (x)
- (f) Standard Management – Cases that do not fall into any one of the other tracks. ()

<u>MARCH 26, 2013</u>	<u>TAMMI MARKOWITZ</u>	<u>PLAINTIFF</u>
Date	Attorney-at-law	Attorney for
<u>215-985-9177</u>	<u>215-985-4169</u>	<u>tmarkowitz@golombhonik.com</u>
Telephone	FAX Number	E-Mail Address

(Civ. 660) 10/02

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: 213 Fox Road, Media, PA 19063

Address of Defendant: 725 Chesterbrook Boulevard, Wayne, PA 19087; 9200 Brookfield Court, Florence,

Place of Accident, Incident or Transaction: KY 41042 U.S. and Commonwealth of Pa

(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?
(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes ☐ No ☒

Does this case involve multidistrict litigation possibilities?

Yes ☒ No ☐

RELATED CASE, IF ANY:

Case Number: _____ Judge _____ Date Terminated: _____

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?
Yes ☐ No ☒
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?
Yes ☐ No ☒
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court?
Yes ☐ No ☒
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?
Yes ☐ No ☒

CIVIL: (Place ☒ in ONE CATEGORY ONLY)

A. Federal Question Cases:

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☐ All other Federal Question Cases
(Please specify) _____

B. Diversity Jurisdiction Cases:

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☐ Products Liability
8. ☐ Products Liability — Asbestos
9. ☒ All other Diversity Cases

(Please specify) CAFA Violation of
Pennsylvania's Unfair Trade Practice and
Consumer Protection Law, 73 Pa. Stat. Section
201-1 et seq

ARBITRATION CERTIFICATION

(Check Appropriate Category)

I, Tammi Markowitz, Esquire

counsel of record do hereby certify:

- ☐ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs;
- ☐ Relief other than monetary damages is sought

DATE: 3/26/13

Tammi Markowitz
Attorney-at-Law

84822

Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 3/26/13

Tammi Markowitz
Attorney-at-Law

84822

Attorney I.D.#

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

Allyson Netwall on behalf of herself and all
others similarly situated,

Plaintiff,

v.

SHIRE U.S., INC., a New Jersey Corporation,
SHIRE, LLC, a Kentucky Limited Liability
Company, and DOES 1 through 100, inclusive,

Defendants.

No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Plaintiff, Allyson Netwall individually and on behalf of all others similarly situated brings this action against Defendants Shire LLC and Shire U.S., Inc. (collectively, “Shire” or “Defendants”), and alleges, based on personal knowledge, investigation, and information and belief, as follows:

I. NATURE OF ACTION

1. This is a putative class action comprised of consumer indirect purchasers of Adderall XR (“AXR”), a popular prescription medication prescribed to treat attention deficit hyperactivity disorder (“ADHD”).

2. Defendants, Shire, are the manufacture of brand-name AXR. Defendants sell AXR under the brand name Adderall XR and also sell it as an “Authorized Generic” to generic companies to sell as a generic product.

3. Though other companies were able to bring an Authorized Generic to the market in 2009, Defendants engaged in a fraudulent scheme meant to delay the entry of generic competition and then to restrict the supply of generic competition. Namely, Defendants filed a sham patent litigation, constructed anticompetitive reverse payment agreements with generic

competitors, and then proceeded to unlawfully breach agreements to supply said competitors with materials to manufacture generic AXR, cutting off supply of cheaper-priced generic AXR to consumers.

4. Defendants' conduct constitutes an illegal restraint of trade and/or attempt at monopolization in violation of antitrust statutes.

5. Additionally, Defendants' fraudulent and deceptive conduct harmed consumers by restricting supply of generic AXR and forcing many to purchase the far more expensive brand-name medication sold by Defendants.

6. Plaintiff therefore brings this action on behalf of himself and a nationwide class of indirect purchasers of AXR, asserting that Defendants' unfair, unlawful, deceptive and anti-competitive behavior violates Consumer Protection Laws and common law as set forth below.

II. PARTIES

7. Plaintiff Allyson Netwall is, and at all times relevant hereto was, an individual residing in Delaware County, Pennsylvania. During the Class Period, Plaintiff purchased AXR in Delaware County, Pennsylvania for personal use, and not for resale. .

8. Defendant Shire U.S., Inc. is a New Jersey corporation with its principal place of business and headquarters at 725 Chesterbrook Blvd., Wayne, Pennsylvania 19087. Throughout the Class Period, Shire U.S., Inc. marketed and sold AXR in Pennsylvania and elsewhere. Upon information and belief, Shire U.S., Inc. is the manufacturer and distributor of Adderall XR. Further, upon information and belief, Shire U.S., Inc. maintains Shire's U.S. headquarters in Pennsylvania.

9. Defendant Shire LLC is a Kentucky limited liability company with its principal place of business at 9200 Brookfield Court, Florence, Kentucky 41042. Shire is a successor

entity to Shire Laboratories, Inc., a party to the agreements at issue in this case. Shire develops, manufactures, and sells brand and generic pharmaceutical products in the United States. Among the brand pharmaceutical products manufactured and sold by Shire is AXR, the pharmaceutical product that is at issue in this action. Throughout the Class Period, Shire LLC marketed and sold AXR in Pennsylvania and elsewhere.

10. The true names and capacities, whether individual, corporate, associated or otherwise of certain manufacturers, distributors, or their alter egos sued herein as DOES 1 through 100 inclusive are presently unknown to Plaintiff who therefore sue these Defendants by fictitious names. Plaintiff will seek leave of this Court to amend the Complaint to show their true names and capacities when the same have been ascertained. Plaintiff is informed and believes and based thereon alleges that DOES 1 through 100 were or are, in some manner or way, responsible for and liable to Plaintiff for the events, happenings, and damages hereinafter set forth below.

11. Plaintiff is informed and believes and based thereon alleges that at all times relevant herein each of the Defendants was the agent, servant, employee, subsidiary, affiliate, partner, assignee, successor-in-interest, alter ego, or other representative of each of the remaining Defendants and was acting in such capacity in doing the things herein complained of and alleged.

III. JURISDICTION AND VENUE

12. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(d) because the matter in controversy exceeds the sum of \$5,000,000, exclusive of interest and costs, and is a class action in which members of the Class of Plaintiffs are citizens of a State different from the Defendants.

13. Defendant has sufficient minimum contacts with Pennsylvania or otherwise intentionally avails itself of the consumer markets within Pennsylvania through the promotion,

sale, marketing, and/or distribution of its products in Pennsylvania to render the exercise of jurisdiction by the Pennsylvania courts permissible under traditional notions of fair play and substantial justice.

14. Defendants transact business within this judicial district, is headquartered in this district and the interstate trade and commerce described herein is carried out, in part, in this district. Plaintiff Netwall and numerous Class Members reside in this district and purchased AXR in this district and were thereby injured and subjected to irreparable harm in this district. Defendants received substantial compensation and profits from sales of AXR in this district. Thus, their liability arose in part in this district. Venue is therefore appropriate under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c).

IV. FACTUAL ALLEGATIONS

A. Adderall XR, Shire, and Generic Competition

15. AXR is a once-a-day psychostimulant drug of the pherethylamine and amphetamine chemical classes indicated for treatment of attention deficit hyperactivity disorder (ADHD).

16. In 1996, Shire released Adderall in an instant release formulation. It quickly became popular as an alternative to methylphenidate (sold under the brand name Ritalin) for treatment of ADHD. Studies indicate that Adderall is slightly more potent and has a longer period of efficacy than Ritalin, especially at lower doses.

17. In 2001, Shire introduced AXR, which added the additional convenience of once-a-day dosing.

18. AXR quickly became a major source of revenue and the flagship product for Shire. A small company founded in 1986, AXR transformed Shire into a major pharmaceutical

company. In the decade following AXR's release, Shire's net sales topped \$6 billion. AXR was a major source of Shire's sales, in 2008 alone accounting for over \$1 billion in sales and nearly half of Shire's overall revenues.

19. Other drug companies sought entry into the AXR markets.

20. In November 2002, Barr Pharmaceuticals (which was acquired by Teva Pharmaceuticals USA, Inc. and will subsequently be referred to as "Teva") filed an Abbreviate New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") to manufacture and sell a generic formulation of AXR it had developed.

21. In September 2003, Impax Laboratories, Inc. ("Impax") filed an ANDA seeking to manufacture and sell its generic version of AXR.

B. Shire's Sham Patent Litigation

22. In February 2003, Shire filed a patent suit against Teva, alleging infringement of its '819 patent ("*Teva I*"). Shire filed a subsequent case against Teva in September 2003, alleging infringement of its '300 patent ("*Teva II*"). Both cases were filed in the Southern District of New York.

23. Shire filed another patent suit against Impax in December 2003, alleging infringement of its '819 and '300 patents for 30 mg dosage ("*Impax I*"). Shire filed a subsequent case against Impax in January 2005, relating to additional dosage forms under the '819 and '300 patents ("*Impax II*"). Both cases were filed in the District of Delaware.

24. Shire's litigation conduct further underscored its bad faith use of the '819 and '300 patent litigation to extend its monopoly. For example, the Court in *Impax I* issued its Markman Order affecting claim construction of the '819 and '300 patents in February 2005. Sensing defeat in light of the Court's order, Shire sought reconsideration, a motion that Impax

correctly described in pleadings as yet another attempt to delay generic entry into the market. The motion for reconsideration was denied.

25. Meanwhile, in a further efforts to undermine the Court's ability in *Impax I* to resolve the patent disputes, in March 2005 (a month after and undoubtedly in response to the unfavorable ruling) Shire claimed that discovery in the Teva litigation uncovered supposed errors in both the '819 and '300 patents, and Shire requested a reissuance of the '819 and '300 patents pursuant to 35 U.S.C. §251.

26. Yet when filing for re-issuance, Shire did not change any of the 42 claims asserted in those patents, but merely added additional claims.

27. The result of the purported "curing" of errors however was to greatly delay and hamper the Court's ability to resolve the case in favor of the generic manufacturers on summary judgment. Put plainly, Shire's '819 and '300 infringement claims were obvious sham claims filed merely to illegally extend its AXR monopoly.

28. In October 2005, Shire filed another patent suit, this time against both Teva and Impax and alleging infringement of its '768 patent ("*Teva/Impax I*"). This case was filed in the Southern District of New York.

29. Shire's '768 patent was not even listed in the FDA's Orange Book, so there was no question that there was no basis for a patent suit by Shire. Under the Hatch-Waxman Act, a generic manufacturer has only infringed a patent if it is listed in the Orange Book; otherwise, generic manufacturers have a safe harbor in their preparation activities and there is no infringement until the generic manufacturer actually markets its product.

30. Further, the release-mechanism technology covered by the '768 patent, upon information and belief, was not even employed by Shire in the AXR product. Both in procedure

and in substance, the '768 patent suit was a sham meant to illegally extend Shire's AXR monopoly.

31. In the midst of its sham patent litigation, Shire's CEO Matt Emmens, in a remarkable moment of candor, described in a November 2005 interview his "tactics" for thwarting generic competition for AXR:

The US is also where the lawyers are, and Mr. Emmens has had to spend a lot of time with them as Shire tries to defend its patents on Adderall, which most analysts forecast will face copycat competition after a courtroom showdown beginning in January. If a copycat version is allowed on the market, Adderall prices will certainly collapse. US parents, insurers and healthcare authorities might very much like that. Mr. Emmens' task is to delay that until Shire's new products have established themselves.

Pharmaceuticals companies expend a great deal of brainpower on tactics for maintaining their monopoly positions, and Shire is trying every tactic in the book. It is pretty pleased with itself to date. It has filed extra patents on the way Adderall is made and is suing the generic drug makers for infringement of that and other patents. And it is asking regulators to insist that the generics firms conduct human trials before being allowed to launch. This last tactic is "pretty elegant", Mr. Emmens says with a smile.

He has experience of this sort of battle, having worked in the joint venture between Merck of the US and Astra of Sweden which developed Prilosec, an ulcer drug which became the world's best-selling medicine. AstraZeneca managed to tie up the manufacturers of generic Prilosec in the courts for nearly two years after the core patents expired, thanks to a plan put in place many years before.

Stephen Foley, *Matt Emmens: Shire Pharmaceuticals chief focuses his attention on drugs deficit*, The Independent, Nov. 12, 2005.

32. In March 2006, Shire filed a patent case against Teva (who had now merged with Barr), alleging (again) infringement of its '819 and '300 patents ("*Teva III*"). This time, Shire filed in the Eastern District of Pennsylvania.

33. By filing suits alleging patent infringement, Shire was able to avail itself of

various FDA regulations resulting in a 30-month automatic stay of FDA's approval of the Teva and Impax ANDAs.

34. Upon information and belief, Shire's patent litigation was a sham, asserting a patent that is invalid, void or otherwise unenforceable, and Shire used the patent litigation to extend the time during which it maintained a monopoly knowing that its monopoly was in jeopardy.

35. Shire's motivation is obvious. Absent its sham litigation and dilatory litigation tactics, the patent litigation may have been resolved in favor of Teva or Impax before the conclusion of the 30-month stay, or the generic manufacturers might proceed to take the drug to market at conclusion of the stay "at risk" even while the patent lawsuits were pending. Of course, the availability of a much cheaper generic would have profound implications for Shire's bottom line, likely causing it to lose ninety (90) percent of the market share for its blockbuster drug.

C. Shire's Reverse Payment Agreements with Teva and Impax

36. In 2006, Shire settled the patent litigation with Teva and with Impax. As part of the voluntary settlements, Shire made various payments to both Teva and Impax and the generic manufacturers agreed not to launch any generic AXR products until April (Teva) and October (Impax) of 2009. Thus, Shire was able to extend its monopoly for three more years.

37. In addition, Shire agreed to provide Teva and Impax with patent licenses so that they could legally sell Shire's formulation of AXR as an Authorized Generic in 2009, in the event the FDA had not yet approved Teva's and Impax's ANDA's for their own generic AXR. Shire would receive a royalty payment based on sales of its authorized generic AXR sold by Teva and/or Impax. Thus Shire retained complete control over the supply of AXR profiting from

sales of the Brand and Authorized Generic product.

38. Further, the agreement contained a requirement contract component, in that Shire agreed to meet Teva's and Impax's supply requirement and provide AXR directly to the two generic companies. Because the FDA had not yet approved the Teva and Impax ANDAs in 2009, they would sell AXR manufactured by Shire as Authorized Generics.

39. The only difference between brand-name and generic AXR would be the trade dress and the price of each product. Shire continued to sell the brand product at a substantially higher price than the Authorized Generic. This further underscores the anticompetitive reasons that Shire was able to maintain such a large market share even though their product was much more expensive yet identical to that marketed by Teva and Impax.

40. Upon information and belief, the three-year extension of Shire's monopoly imposed a substantial cost on consumers and conferred a benefit to Shire. Through the settlement agreements, Shire provided consideration to Teva and Impax in exchange for their delay into the market.

41. Other generic manufacturers followed Teva and Impax by filing ANDAs for generic AXR, and Shire treated them in the same manner as it did Teva and Impax, by filing sham patent infringement litigation and then reaching settlements prior to any ruling on the validity of Shire's patents.

D. Shire's Intentional Breach of the Reverse Payment Agreement

42. Even after enjoying an extended monopoly over the market, on information and belief, Shire willfully perpetuated a fraudulent scheme intended to further monopolize the market. This scheme included, among other things limiting the supply of the AXR product, such that Teva and Impax were unable to meet demand for the Authorized Generic.

43. Shire refused to supply AXR to Teva in violation of the Shire-Teva agreement.

Upon information and belief:

a. Teva introduced its generic AXR product in April 1, 2009 at prices below those charged for brand name AXR, and quickly acquired a majority (approximately sixty percent) of the AXR market.

b. As required by their agreement with Shire, Teva on or around July 1, 2009 sent Shire a 12-month forecast of the predicted supply of AXR Teva would need. Along with that forecast was a purchase order (binding on Shire) for the months of October, November, and December 2009.

c. Shire, however, refused to honor the binding purchase order, and on or around August 28, 2009 notified Teva that it would not deliver the amount requested in the purchase order and would be delivering instead a much lower amount.

d. Then, on or around October 2, 2009, Shire notified Teva that it would not even be providing the much-lower amounts of AXR it had promised in August. Meanwhile, Shire continued to provide the market with AXR to be sold under its brand-name (and more expensive) label. In short, through its deceptive and anticompetitive behavior Shire forced consumers to purchase an identical product for a much higher price.

e. A few days later, on or around October 5, 2009, Shire employee Jeff Cooperrider told Teva employee Jeff Keyser that the reason behind Shire's failure to deliver the product to Teva was Shire's management's decision to keep the product for itself.

f. By failing to deliver the amount of AXR purchased in the July 2009 purchase order, Shire unlawfully breached its agreement with Teva. This breach continued via Shire's practice of restricting the supply from October 2009 on with the purpose and effect of

hindering Teva's ability and incentive to compete in the AXR market.

44. Shire also refused to supply AXR to Impax in violation of the Shire-Impax agreement. Upon information and belief:

a. Impax, whose AXR product was scheduled to debut on or around October 1, 2009, notified Shire in the months leading up to October of its intent to rely upon Shire to supply Impax's AXR product. On information and belief, Impax timely submitted its purchase order for the amount needed for the initial launch, and continued to timely submit purchase orders thereafter based upon its forecasts.

b. Starting in 2009, Shire failed to timely fill Impax's purchase orders. Upon information and belief, the problem intensified in 2010 when Shire not only failed to timely deliver product, but in many instances delivered less than what was ordered or delivered none at all. These repeated breaches of the agreement had the purpose and effect of hindering Impax's ability and incentive to compete in the AXR market.

c. According to court documents filed by Impax, Shire's behavior had devastating effects. As noted by the company:

Impax consistently lacked sufficient supply of generic AXR. As a result of this lack of supply, Impax was unable to fill many of its customers' purchase orders. Impax also was forced to ration product to its customers or delay delivering product to its customers as a result of Shire's failure to supply. Impax's customers would have ordered more generic AXR if it were available. On several occasions, customers approached Impax seeking to purchase more generic AXR, but Impax had to turn them away before any purchase orders were placed because it had no stock available.

.....

As a result of Shire's failure to supply Impax with generic AXR, Impax lost sales to existing customers, lost the opportunity to execute more favorable contracts with its customers, and was unable to solicit additional customers.

....

By starving Impax of supply, Shire ensured that Impax could not compete. Without sufficient supply Impax was unable to fill the orders of its customers, unable to provide those customers with additional product they wanted to buy, and unable to solicit new customers. Shire, on the other hand, has been able to line its pockets with tens of millions of dollars every month from sales of branded AXR by refusing to fill Impax's orders and keeping supply for itself. Indeed, as a result of Shire's actions, more than two years after generic entry, Shire's branded AXR accounts for approximately 40% of the total AXR market.

45. Upon information and belief, had Shire met its obligation to supply AXR to Teva and Impax, the generic manufacturers would have captured roughly ninety (90) percent of the market. But in or around late 2009, Shire began improperly limiting the supply of AXR to the generic manufacturers, such that they were only able to capture little more than half of the market.

46. Thus, even though consumers faced much more expensive co-pays for brand name medication, upon information and belief Shire was able to maintain a fifty (50) percent market share, which is unheard of following the availability of a cheaper, generic version of the drug.

47. By intentionally, unlawfully and fraudulently breaching the agreement, and ensuring that supply of generic AXR did not meet demand, Shire forced tens if not hundreds of thousands of consumers to expend significantly more money and purchase Shire's branded product.

48. Further, upon information and belief, with the supply of generic alternatives dwindling, Shire raised the price of brand name AXR while simultaneously eliminating discounts and rebates. Thus not only was Shire able to maintain its monopoly prices, but through its anticompetitive acts, it was able to *raise* them.

E. Shire's Deceptive And Fraudulent Supply Shortage Scheme

49. Upon information and belief, the AXR shortage was the result of a fraudulent scheme on the part of Shire's management who created the shortage in order to increase the brand name market for the drug, as Shire controlled the supply for AXR—both brand name and generic.

50. Indeed, Shire had no legitimate justification for its intentional breach of its agreements with Teva and Impax. The excuses offered by Shire, for these breaches were merely deceptive pretexts.

51. Specifically, Shire publicly claimed that the AXR shortage was due to the Drug Enforcement Administration's ("DEA") failure to set a manufacturing quota high enough to meet demand and that the supply agreements allowed Shire to "fairly" and "reasonably" allocate the artificially restricted supply of AXR among Shire, Teva, and Impax. However, this statement is wholly deceptive.

52. The DEA has rejected Shire's assertion that the DEA quota created the AXR shortage. DEA officials have repeatedly stated that any shortage of pills to sell to generic competitors was not the result of the DEA quota but Shire's unilateral decision to allocate more pills to itself.

53. Moreover, on or about October 5, 2009, a Shire employee, Jeff Cooperrider, admitted to a Teva employee, Jeff Keyser, that Shire was not going to deliver the product it was obligated to supply because Shire's senior management had decided that Shire wanted to keep the product for itself.

54. As evidence of Shire's anticompetitive effect, Shire in late 2010 was actually able to *raise* the price of AXR. Even after raising the prices and increasing its own revenue, Shire

still refused to reallocate the supply of AXR to Teva and Impax. During this time Shire actually increased its self-allocation of AXR from forty (40) percent of the total AXR allocated to fifty (50) percent. In this sense, Shire's breach of its supply agreements allowed it to charge artificially inflated prices. Even while Shire raised its prices, it was able to increase its market share.

55. As a result, Shire reported in the third quarter of 2010 that AXR sales had increased forty-one (41) percent to \$99.7 million (for the quarter). The sales numbers continued to climb, and in the first two quarters of 2011 Shire reported AXR sales of \$111 million and \$146.9 million.

F. Factual Allegations as to Named Plaintiff

56. Plaintiff, Allyson Netwall is a resident of Delaware County, Pennsylvania was first prescribed AXR in or around 2003 and continues to take it through the present.

57. Ms. Netwall was an indirect purchaser of AXR.

58. Ms. Netwall had an insurance policy through Keystone Blue Cross and Blue Shield. Under the policy, Ms. Netwall had to spend significantly more for brand name medication where there was an FDA-approved generic. The co-pay for brand name medications, the amount Ms. Netwall had to spend, was more for brand-name drugs than for generic drugs.

59. On several occasions during the Class Period, Plaintiff Netwall was unable to procure generic AXR due to a lack of generic supply, and had to expend considerably more personal funds to purchase the brand name AXR.

V. CLASS REPRESENTATION ALLEGATIONS

A. Class Definition

60. Plaintiff bring this action pursuant to Federal Rules of Civil Procedure 23(b)(2)

and (b)(3) on behalf of herself and on behalf of a Nationwide Class of similarly situated persons defined below. The relevant time period for the Class is April 1, 2009 to the present ("the Class Period"). The proposed National Class consists of:

All persons residing in the United States and its territories, who purchased brand name AXR for personal use and not for resale during the time period of April 1, 2009 through the present ("the Class").

61. Plaintiff also seeks to represent a Pennsylvania subclass that includes:

All persons residing in the Commonwealth of Pennsylvania who purchased brand name AXR for personal use and not for resale during the time period of April 1, 2009 through the present ("the Subclass").

62. Excluded from the National Class and the Pennsylvania Subclass are governmental entities, Defendants, any entity in which Defendants have a controlling interest, and Defendants' officers, directors, affiliates, legal representatives, employees, co-conspirators, successors, subsidiaries and assigns. Also excluded from the Class and Subclass are any judge, justice or judicial officer presiding over this matter.

63. Said definition may be further defined or amended by additional pleadings, evidentiary hearings, a class certification hearing, and orders of this Court.

B. Fed. R. Civ. P. 23(a) Factors

64. **Numerosity.** The members of the Class and Subclass are so numerous that separate joinder of each member is impracticable. Plaintiff does not know the exact number of members in the Class or Subclass, but based upon information and belief, Plaintiff reasonably believes that Class and Subclass members number at a minimum in the thousands.

65. **Commonality.** The claims of Plaintiff raise questions of law or fact common to the questions of law or fact raised by the claims of each member of the Class and the Subclass. Plaintiff's claims arise from the same practice or course of conduct that gives rise to the claims

of the Class and Subclass members. The questions of law and fact common to Plaintiff and the Class and Subclass predominate over questions affecting only individual Class and Subclass members, and include, but are not limited to, the following:

- a. Whether Shire's patent infringement lawsuits filed against Teva, Impax and others were filed were fraudulent and deceptive and for the improper purpose of preventing entry of competing generic products into the market.
- b. Whether Defendants' intentional, fraudulent and deceptive breach of the supply agreements with Teva and Impax violates Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("PUTPCPL"), 73 Pa. Stat. § 201-1, *et seq*
- c. Whether the Defendants perpetuated a fraudulent scheme to create an AXR supply shortage in violation of Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("PUTPCPL"), 73 Pa. Stat. § 201-1, *et seq*
- d. Whether Plaintiff, the Class and the Subclass have been injured as a result of Defendants' anti-competitive, fraudulent and deceptive conduct, and the amount of damages.
- e. Whether Defendants were unjustly enriched to the detriment of the Class, entitling Plaintiff and the Class to disgorgement of all monies resulting there from.

66. **Typicality.** The claims of Plaintiff are typical of the claims of each member of the Class and the Subclass. Defendants engaged in a standardized course of conduct affecting the Class and Subclass Members, and Plaintiff's alleged injuries arise out of that conduct. All Class and Subclass Members, including Plaintiff, have the same or similar injury to their property (i.e. paying higher prices for AXR) as a result of Defendants' anti-competitive conduct.

67. **Adequacy.** Plaintiff can fairly and adequately protect and represent the interests of each member of the Class and Subclass. Plaintiff fit within the class definition and her interests do not conflict with the interests of the members of the Class or Subclass he seeks to represent. Plaintiff is represented by experienced and able attorneys. The undersigned Class Counsel have litigated numerous class actions and complex cases and intend to prosecute this

action vigorously for the benefit of the entire Class and Subclass. Plaintiff and Class Counsel can and will fairly and adequately protect the interests of all members of the Class and Subclass.

C. Fed. R. Civ. P. 23(b)(2) Factors

68. Defendants acted on grounds generally applicable to the entire Class and Subclass, thereby making final injunctive relief and/or corresponding declaratory relief appropriate with respect to the Class as a whole and the Subclass. The prosecution of separate actions by individual Class or Subclass Members would create the risk of inconsistent or varying adjudications with respect to individual members of the Class and Subclass that would establish incompatible standards of conduct for Defendants.

69. Injunctive relief is necessary to prevent further anti-competitive conduct by Defendants. Money damages alone will not afford adequate and complete relief, and injunctive relief is necessary to restrain Defendants from continuing to engage in conduct which restrains, suppresses, and/or eliminates competition in the United States and Pennsylvania for the sale of AXR.

D. Fed. R. Civ. P. 23(b)(3) Factors

70. **Common issues predominate:** As set forth in detail above, common issues of fact and law predominate because all of Plaintiff's claims are based on identical anti-competitive, deceptive and fraudulent conduct.

71. **Superiority:** Additionally, a class action is superior to other available methods for fair and efficient adjudication of the controversy. The damages sought by each Class and Subclass Member are such that individual prosecution would prove burdensome and expensive given the complex and extensive litigation necessitated by Defendants' conduct. It would be virtually impossible for the members of the Class and Subclass to effectively redress the wrongs

done to them on an individual basis. Even if the members of the Class and Subclass themselves could afford such individual litigation, it would be an unnecessary burden on the courts.

72. The trial and litigation of Plaintiff's claims are manageable. Individualized litigation presents a potential for inconsistent or contradictory judgments and increases the delay and expense to all parties and to the court system presented by the legal and factual issues raised by Defendants' conduct. By contrast, the class action device will result in substantial benefits to the litigants and the Court by allowing the Court to resolve numerous individual claims based upon a single set of proof in just one case.

73. Further, Defendants have acted on grounds generally applicable to the Class and Subclass, thereby making final injunctive relief with respect to the Class as a whole appropriate. Moreover, on information and belief, Plaintiff alleges that the conduct complained of herein is substantially likely to continue in the future if an injunction is not entered.

74. **Notice to the Class:** Notice to the Class and Subclass may be made by publication.

VI. CAUSES OF ACTION

COUNT I: PENNSYLVANIA'S UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW, 73 PA. STAT. § 201-1, *ET. SEQ.* (On Behalf Of Plaintiff And The Subclass)

75. Plaintiff repeats and realleges the allegations set forth above, and incorporates the same as if set forth herein at length.

76. Plaintiff brings this count on her own behalf and on behalf of all Subclass members.

77. Plaintiff and Subclass members purchased AXR for personal use, and not for resale. .

78. Defendants engaged in fraudulent and deceptive conduct in violation of PUTPCPL, 73 Pa. Stat. § 201-1 *et. seq.* by filing sham patent litigation against Teva and Impax, in order to extend the time during which it maintained a monopoly knowing that its monopoly was in jeopardy.

79. Additionally, Defendants' engaged in fraudulent and deceptive conduct in violation of PUTPCPL, 73 Pa. Stat. § 201-1 *et. seq.* by entering into supply agreements with Teva and Impax with the intention of breaching the supply agreements.

80. Additionally, Defendants' engaged in fraudulent and deceptive conduct in violation of PUTPCPL, 73 Pa. Stat. § 201-1 *et. seq.* when they intentionally breached the supply agreements with the generic manufacturers, Teva and Impax, in order to artificially control the supply and cost of AXR in the marketplace. Defendants' intentional breach of the agreements with Teva and Impax restricted generic AXR output and furthered Defendants' monopolization of the AXR market.

81. Defendants further engaged in fraudulent and deceptive conduct when they falsely and publically claimed that they breached the supply agreements with Teva and Impax because the DEA failed to set a manufacturing quota high enough to meet demand.

82. The goal, purpose and/or effect of Defendants' fraudulent and deceptive scheme was to prevent, delay, and/or minimize the success of the entry of generic AXR competitors, who would have sold generic versions nationwide and in Pennsylvania at prices significantly below Defendants' prices for AXR.

83. As a direct and proximate result of Defendants' anticompetitive, deceptive and fraudulent conduct, Plaintiff and Subclass members were deprived of the opportunity to purchase a generic version of AXR, from August 28, 2009 to the present.

84. Plaintiff and members of the Subclass have been injured in their business and property by reason of Defendants' anticompetitive, deceptive and fraudulent acts alleged in this Count. The injury consists of paying higher prices for AXR prescription drugs than they would have paid in the absence of these violations. This injury is of the type 73 Pa. Stat. § 201-1 *et. seq.* was designed to prevent and directly results from Defendants' unlawful conduct.

85. In addition to actual damages, Plaintiff and the Subclass are entitled to declaratory and injunctive relief as well as reasonable attorney's fees and costs pursuant to 73 Pa. Stat §201-9.2

COUNT TWO
UNJUST ENRICHMENT
(On Behalf Of Plaintiff, The Class And The Subclass)

86. Plaintiff repeats and realleges the allegations set forth above, and incorporate the same as if set forth herein at length.

87. Plaintiff bring this count on her own behalf and on behalf of all class members.

88. Defendants have financially benefited from the monopoly profits on the sale of AXR resulting from their unlawful and inequitable acts alleged in this Complaint.

89. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for AXR by Plaintiff and members of the Class.

90. Plaintiff and the Class have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of the Plaintiff and the Class.

91. The economic benefits of overcharges and unlawful monopoly profits derived by Defendants through charging supra-competitive and artificially inflated prices for AXR is a direct and proximate result of Defendants' unlawful and inequitable practices.

92. The financial benefits derived by Defendants rightfully belong to Plaintiff and the Class, as Plaintiff and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Defendants.

93. It would be inequitable and violative of the law of the Commonwealth of Pennsylvania for the Defendants to be permitted to retain any of the overcharges for AXR derived from Defendants' unfair and inequitable practices alleged in this Complaint.

94. Defendants should be compelled to disgorge all unlawful or inequitable proceeds received by them.

95. Plaintiff and the Class have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of herself and on behalf of the members of the Class and Subclass defined herein, pray for judgment and relief on all Causes of Action as follows:

A. An order certifying the proposed Nationwide Class and the Pennsylvania Subclass and appointing Plaintiff Allyson Netwall and the undersigned counsel of record to represent each class;

B. The acts alleged herein be adjudged and decreed to be a deceptive and/or fraudulent business practices violating PUTPCPL;

C. That judgment be entered against Defendants, and each of them jointly and severally, for damages as a result of Defendants' PUTPCPL violations;

D. That judgment be entered against Defendants and in favor of Plaintiff and the Class on the Plaintiff's PUTPCPL claim,

E. An order enjoining Defendants from pursuing the policies, acts, and practices complained of herein;

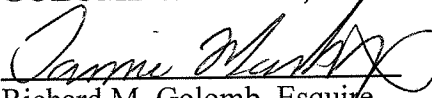
- F. Actual damages;
- G. For pre-judgment interest from the date of filing this suit;
- H. Reasonable attorneys' fees;
- I. Costs of this suit; and
- J. Such other and further relief as the Court may deem necessary or appropriate.

JURY TRIAL DEMANDED

April 1, 2013

Respectfully submitted,

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